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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,524	06/27/2000	PETER JOHN BURNE	0769.00140	8239

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EXAMINER	
PADMANABHAN, KARTIC	
ART UNIT	**PAPER NUMBER**
1641	8

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,524	Applicant(s) BURNE ET AL.	
	Examiner Kartic Padmanabhan	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82-150* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82-150* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 82-96, 99-103, 107, and 146-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman (US Pat. 5,501,955) in view of May et al. (US Pat. 5,622,871).

Bergman teaches a method for detecting the presence of autoantibodies in biological

fluids, such as serum (col. 3, line 67) by a) providing an antigen specific for autoantibody such as thyroid peroxidase; b) providing a substrate having an immobilized antibody specific for the antigen; c) contacting the antigen with a body fluid sample to allow binding of the complex; d) allowing the mixture to flow into the test tube to contact the immobilized monoclonal antibody; e) providing labeling means such as labeled non-immobilized monoclonal antibody to allow binding to the complex, which is an indication of the presence of autoantibody in a sample of body fluid (fig 1 and cols. 3-4). The reference also teaches various formats for the detection of autoantibodies. The reference states that sandwich complexes with a specification of suitable properties for detection of certain autoantibodies can be tailored when both the immobilized and labeled antibodies are monoclonal (col. 4, lines 50-55). The reference also teaches three different competitive situations involving analyte-antibody analysis. In Fig 1, analyte competes for the same binding site as the immobilized antibody. In Fig 2, analyte competes for the same binding site as the labeled antibody. In Fig 3, analyte competes for the same binding site as both labeled and immobilized antibodies. The reference does not teach the use of a test strip as the substrate.

May et al. teach a test strip format in which assays involving specific binding or immunoassays may be formatted in a test strip to provide convenience for home or clinical use. A sample may be applied to a portion of the test strip and allowed to permeate through the test material. A control zone may be designed to detect unrelated signal to the user that the device is working. The sample progresses to a detection zone where a specific binding partner for the sample analyte is immobilized. Analyte concentration may be determined by a labeled reagent that can be incorporated within the test strip or applied thereto (col. 1, lines 35-60). Direct labels such as metallic sols (e.g. gold) can be used for an analytical result (col. 5, lines 29-32). The

substrates involved in the test strip are porous membranes such as nitrocellulose (col. 7, lines 5-10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Bergman et al. by incorporating the method into a test strip, as taught by May et al. because the use of a test strip provides for rapid analytical results with a great degree of convenience and little required involvement from the user.

5. Claims 104-106 and 109-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman (US Pat. 5,501,955) in view of May et al. (US Pat. 5,622,871) as applied to claims 82-96, 99-103, 107, and 146-149 above, and further in view of Janeway et al. (Immunobiology 3rd ed.).

Bergman and May et al. teach a modified detection method as discussed above. Although the references do not teach the detection of two autoantibodies in the same assay, it is conventional in the art to extract crude thyroid peroxidase antigen comprising specific epitopic sites for binding of specific autoantibodies. These components may be incorporated into an immunoassay format for the detection of specific analyte antibodies. Janeway et al. teach multivalent antigens and antibody binding, as well as monoclonal antibody production (2:12 and 2:17).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the modified method of Bergman and May et al. by providing a multivalent antigen and monoclonal antibodies specific for the pertinent epitopes as taught by Janeway et al. because this assay method provides for a selective and sensitive assay for dual analyte detection.

6. Claims 115-145 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman (US Pat. 5,501,955) in view of May et al. (US Pat. 5,622,871) as applied to claims 82-96, 99-103, 107, and 146-149 above, and further in view of Foster et al. (US Pat. 4,444,879).

Bergman and May et al. teach a modified detection method as discussed above. However, the references do not teach a kit.

Foster et al. teach a kit in which an immunoassay of the invention is incorporated. The kit contains a substrate, buffers, and other reagents, controls, instructions, containers, and any other pertinent components of the immunoassay of the invention (col. 15, lines 12-34).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the modified method of Bergman and May et al. by incorporating a kit containing all the necessary reagents and supplies, as taught by Foster et al. because kits are well known in the art and are widely recognized for their advantages of economy and convenience.

7. Claims 97-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman (US Pat. 5,501,955) in view of May et al. (US Pat. 5,622,871) as applied to claims 82-96, 99-103, 107, and 146-149 above, and further in view of Bergmann et al. (WO 95/06258).

Bergman and May et al. teach a modified detection method as discussed above. However, the references do not teach mixing test reagents with sample before addition to substrate.

Bergmann et al. teach mixing and incubating sample in an uncoated test tube with thyroid stimulating hormone receptor and a competitor before addition to monoclonal antibody bound substrate. Addition of labeled antibody and detection of the complex also occurs (page 16, lines 39-40 and page 17, lines 1-3).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the modified method of Bergmann and May et al. by mixing sample with the pertinent assay binding components before addition to substrate as taught by Bergmann et al. because the incubation step before addition to substrate would allow for adequate binding of components to form a complex before addition to substrate containing an immobilized component.

Response to Arguments

8. Applicant's arguments filed September 20, 2002 have been fully considered but they are not persuasive.

9. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., rapid and simple detection methods and kits for use at point of care by non-lab procedures) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. In response to applicant's argument that the prior art does not teach a screening method, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

11. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have been motivated to use the May test strip with Berman because of the recognized advantages of a test-strip format. There is no reason to believe that the complex formed in Bergman would not migrate through the test strip and bind to the immobilized antibody in the detection zone, especially when considering that May also assays biological fluids. Applicant's general assertions that there is no guidance to modify the invention of Bergman into a test strip is moot, as such a modification is viewed as routine and well-known in the art, and applicant has not provided evidence to the contrary.

12. It is also noted that applicant has only addressed 3 claims in the response to the last office action, and has neglected to treat independent claim 115 at all. In addition, only the rejection over Bergman in view of May et al. has been addressed. Therefore, since the rejection over Bergman in view of May et al. has been maintained, so too have all the other 103 rejections.

Conclusion

Claims 82-150 are rejected.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641
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April 18, 2002

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
4/19/02